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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/840,485 04/23/01 BIGBIE

R AM100123

025291 HM12/0925
AMERICAN HOME PRODUCTS CORPORATION
FIVE GIRALDA FARMS
PATENT LAW
MADISON N.J. 07940

EXAMINER

SHAHNAN-SHAH, K

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/840,485	BIGBIE ET AL.
	Examiner	Art Unit
	Khatol S Shahnan-Shah	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 19 August 2001 and 04 September 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-25 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2, 3

4) Interview Summary (PTO-413) Paper No(s). _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

DETAILED ACTION

1. Information disclosure statements, received 8/19/2001 and 9/4/2001, papers # 2 and 3 are acknowledged.
2. Currently claims 1-25 are pending and under consideration.

Abstract

3. The abstract of the disclosure is objected to because it constitutes more than one paragraph. Correction is required. See MPEP § 608.01(b).

Specification Informalities

4. The disclosure is objected to because of the following informalities.

The use of the trade marks have been noted in this application (specification page 11, lines 15, 19, 28 and page 14, lines 18, 21). It should have a trade mark sign wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Applicants' cooperation is requested to review the entire specification for all possible minor errors and correct any errors of which applicant may become aware of in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 23 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for equine dermal cells, does not reasonably provide enablement for all cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with this claim. Enablement is considered in view of the Wands factors (MPEP) 2164.01(a). Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples (6) the quantity of experimentation, (7) the relative skill of those in the art, and (8) the breadth of the claims.

In the instant invention the breadth of the claim 23 is extremely broad. Claim 23 recites “growing a monolayer of cells....”. This encompasses any cell (i.e. mammalian, bacterial, insects, etc.). However the specification discloses only equine dermal cells (page 22, example 5). Specification does not define all cells as claimed except mammalian cells (page 8). Specification fails to provide further guidance in this regard. Therefore, one skilled in the art could not make and/or use the invention without undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Marsh et al. (U.S. Patent Number 6,071,737 and WIPO Patent Number WO 99/47927).

Claims 1, 3-11 are drawn to an immunogenically active component and a vaccine composition, which comprises an inactivated equine Neospora cells such as tachyzoites.

Marsh et al disclose immunogenically active components and a vaccine composition, which comprises an inactivated equine Neospora, cells such as tachyzoites (see abstracts of patents 6,071,737 and WO 99/47927).

Marsh et al in patent 6,071,737 disclose tachyzoites of Neospora equi isolates removed from an adult horse with EPM (Equine protozoal myeloencephalitis) were cultured on monkey kidney cells (Vero) and the protein and nucleic acid were isolated (see columns 7 and 8). Immunogenic active components were prepared (column 10). They also disclose vaccine compositions, a variety of pharmaceutically acceptable carriers and adjuvants (see column 14). Adjusting the unit dosages, volumes, and percentages are well known in the art of immunology and pharmaceuticals.

Marsh et al in patent WO 99/47927 disclose the same invention as stated above (see claims specially claims 4, 5, 8, 15, 21, 25).

Since the office does not have the facilities for examining and comparing applicants' products with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i. e., that the products of prior art do not possess the same material structure and functional characteristics of the claimed products). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

7. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Granstrom et al.

(Journal Veterinary Diagnostic Investigation, Vol.5, pp. 88-90, 1993).

Claim 2 is drawn to an immunogenically active component, which comprises inactivated *Sarcocystis neurona*.

Granstrom et al. teach antigens of cultured *Sarcocystis neurona* merozoites. They teach eight different immunogenically active components of *Sarcocystis neurona* (see abstract).

8. Claims 12-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Marsh et al in patent (WO 99/47927) and Azumendi (WO 97/299770).

Claims 12-22 are drawn to vaccine compositions and methods of prevention EPM (Equine protozoal myeloencephalitis) in equine administering immunogenically active components and vaccine compositions, which comprise inactivated equine *Neospora* and *Sarcocystis neurona* cells.

Azumendi disclose a vaccine and a method of vaccination against infections produced by *Sarcocystis neurona* (see abstract and claims 1-7 and 20- 22).

Marsh et al. disclose immunological compositions and the method of their use for treatment and prevention of equine *Neospora* infections (see abstract and claims 25,26, 29, and 30).

Since the office does not have the facilities for examining and comparing applicants' compositions and methods with the compositions and methods of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed compositions and methods and the compositions and methods of the prior art (i. e., that the compositions and methods of prior art do not possess the same, steps, material and functional characteristics of the claimed compositions and methods). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA

1977) and In re Fitzgerald et al., 205 USPQ 594.

9. Claims 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Marsh et al. (J. Parasitology, Vol. 85, No. 5, pp. 983-991, 1998).

Claims 23-25 are drawn to a method of cell culture propagation of *Neosopora hughesi* using African Green monkey cells.

Marsh et al. teach a method of cell culture for *Neosopora hughesi* cultivation using (Vero) cells or African Green monkey cells (see page 984).

Since the office does not have the facilities for examining and comparing applicants' cell culture method with the cell culture method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i. e., that the method of prior art does not possess the same, steps, material and functional characteristics of the claimed method). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

10. Claims 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Mansfield et al. (U.S. Patent Number 6,153,394).

Claims 23-25 are drawn to a method of cell culture propagation of *Sarcocystis neurona* using Equine Dermal cells.

Mansfield et al. teach a method of cell culture for *Sarcocystis neurona* cultivation using Equine Dermal cells (see column 5).

Since the office does not have the facilities for examining and comparing applicants' cell culture method with the cell culture method of the prior art, the burden is on the

applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i. e., that the method of prior art does not possess the same, steps, material and functional characteristics of the claimed method). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on Monday through Friday from 7:30 AM - 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah 9/24/01

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

Rodney P. Swartz
RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER